

CLAIMS

1. Self-supporting films comprising:

a) a filmogenic substance consisting of a maltodextrin,

b) a plasticiser,

5 c) an active ingredient for food or pharmaceutical use,
characterised in that said films are free of hydrocolloids.

2. Self-supporting films as claimed in claim 1, characterised in that the maltodextrin (a) has a dextrose content of less than 50 expressed in equivalents.

3. Self-supporting films as claimed in claim 2 wherein said dextrose content is
10 between 11 and 40.

4. Self-supporting films as claimed in any one of claims 1-3, characterised in that the plasticiser is chosen from the class consisting of polyalcohols, citric acid esters, sebacic acid esters or their mixtures.

5. Self-supporting films as claimed in any one of claims 1-4, characterised in that
15 the plasticiser is chosen from the class consisting of propylene glycol, glycerine, sorbitol, maltitol and their relative mixtures.

6. Self-supporting films as claimed in any one of claims 1-5, characterised in that the active principle for food use is an active principle with a breath freshening action and/or indicated for oral hygiene or an active principle suitable for
20 nutritional supplementation.

7. Self-supporting films as claimed in claim 6, characterised in that said active principle for food use is chosen from menthol and eugenol.

8. Self-supporting films as claimed in claim 6 wherein said active principle suitable for nutritional supplementation is chosen from mineral salts normally used for
25 such purpose, and vitamins.

9. Self-supporting films as claimed in claim 8 wherein the vitamin is ascorbic acid.

10. Self-supporting films as claimed in any one of claims 1-5, characterised in that said active principle for therapeutic use is chosen from active principles with essentially topical activity.

30 11. Self-supporting films as claimed in claim 10, characterised in that said active principle is chosen from the class consisting of antibacterial, antimycotic, antiviral

agents and disinfectants of the oral cavity.

12. Self-supporting films as claimed in any one of claims 1-5 wherein the active principle for therapeutic use is chosen from the class consisting of active principles with essentially systemic activity.

5 13. Self-supporting films as claimed in claim 12, characterised in that said active principle with essentially systemic activity is chosen from the class consisting of anti-inflammatory, analgesic, antipsychotic, hypnotic, anxiolytic, antihypertensive, myorelaxant, antimigraine, antiparkinsonian, antiemetic, antihistaminic, beta blocking and antiasthmatic agents.

10 14. Self-supporting films as claimed in either of claims 12 or 13, characterised in that said principle is chosen from the class consisting of: Piroxicam, Ketoprofen, Sodium diclofenac, Tramadol hydrochloride, Morphine, Nifedipine, Diazepam, Lorazepam, Alprazolam, Bromazepam, Triazolam, Lormetazepam, Zolpidem, Paracetamol, Selegiline, Atenolol, Salbutamol, Sumatriptan, Clozapine, Cetirizine,
15 Ondansetron, Fentanyl and their pharmaceutically acceptable salts.

15. Self-supporting films as claimed in any one of claims 1-14, characterised by containing maltodextrin at concentrations between 40 and 80% by weight, plasticiser in concentrations between 15 and 55% by weight and the active principle for food or pharmaceutical use in a quantity between 0.05% and 30% by
20 weight on the total weight of said film.

16. Self-supporting films as claimed in any one of claims 1-15, characterised by containing other excipients chosen from the class consisting of anticaking agents, sweeteners, flavourings, colouring agents, preservatives, acidity regulating systems and mixtures thereof.

25 17. Self-supporting films as claimed in claim 16, characterised in that said antisticking agents are chosen from the class consisting of microcrystalline cellulose, colloidal silica and talc.

18. Process for preparing self-supporting films claimed in any one of claims 1-17, comprising the following steps:

30 i) the maltodextrin, plasticiser and active principle for food or therapeutic use are mixed,

ii) the mixture derived from the preceding step is extruded in an extruder.

19. Process as claimed in claim 18, characterised in that the extrusion step (ii) is preferably conducted at a temperature between 60 and 120°C.

20. Process as claimed in either of claims 18 and 19, characterised by being
5 conducted in a single screw extruder.

21. Process for preparing self-supporting films claimed in any one of claims 1-17, characterised by comprising the following steps:

i) the maltodextrin, plasticiser and the active principle for therapeutic or food use are dispersed in a polar solvent at a temperature between 60 and 105°C,

10 ii) the mixture obtained in the preceding step is rolled onto silicone paper and then dried,

iii) the silicone paper is removed from the film obtained in the preceding step.

22. Process as claimed in claim 21, characterised in that the polar solvent used in step (i) is preferably chosen from the class consisting of water, a water miscible
15 solvent and relative mixtures.

23. Process as claimed in claim 22, characterised in that said solvent consists of water or a water-ethanol mixture.

24. Process as claimed in claim 23, characterised in that the temperature of steps (i) and (ii) is between 60 and 105°C.

20 25. Process for preparing self-supporting films claimed in any one of claims 1-17, comprising the following steps:

i) the maltodextrin, plasticiser and active ingredient for food or therapeutic use are mixed,

ii) the mixture was granulated, sieved and mixed with an anti sticking agent,

25 iii) the granules were stored at least for 12 h,

iv) the granules derived from the preceding step were extruded in an extruder for obtaining the edible film.

26. Process as claimed in claim 25, characterised in that the extrusion step (ii) is preferably conducted at a temperature between 70 and 140°C.

30 27. Process as claimed in either of claims 18 and 19 and 26, characterised by being conducted in a single screw extruder